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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,104

02/14/2006

Ivan Kamiel De Scheerder

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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

07/22/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto.phil@dlapiper.com

Office Action Summary	Application No. 10/595,104	Applicant(s) DE SCHEERDER ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 10-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/14/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Claims 1-9 in the reply filed on 5/18/2009 is acknowledged.
2. Claims 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "a prosthesis", and the claim also recites "a stent or shunt" which is the narrower statement of the range/limitation.

6. Claim 3 recites the broad recitation "an endovascular stent", and the claim also recites "a coronary stent" which is the narrower statement of the range/limitation.

7. Claim 4 recites the broad recitation "a wire", and the claim also recites "a hollow wire filled with said therapeutic agent or with a product containing said therapeutic agent", which is the narrower statement of the range/limitation

8. Claim 8 recites the broad recitation "at least .001 $\mu\text{g}/\text{mm}^2$ ", and the claim also recites "at least .1 $\mu\text{g}/\text{mm}^2$ ", "at least .5 $\mu\text{g}/\text{mm}^2$ ", and "at least 2 $\mu\text{g}/\text{mm}^2$ ", which are narrower statements of the range/limitation.

9. Claim 8 also recites a total load of melatonin of "lower than 50 $\mu\text{g}/\text{mm}^2$ ", and the claim also recites "preferably lower than 10 $\mu\text{g}/\text{mm}^2$ " and "preferably lower than 6 $\mu\text{g}/\text{mm}^2$ ", which are narrower statements of the range/limitation.

10. Claim 9 recites the broad recitation "at least 6 hours", and the claim also recites "at least one week", which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaplan (WO 98/30255) as cited in applicants' IDS.

13. Kaplan discloses a stent comprising a releasable therapeutic agent comprising melatonin (col. 6 lines 5-18), the therapeutic agent being present in an effective amount to modify the healing response of the vessel wall after tissue injury (Kaplan discloses the use of melatonin to treat restenosis).

14. The melatonin is coated on the stent. The stent can be a wire stent (see pg. 9 lines 2-10, noting that U.S. Pat. No.: 5342348 is a wire stent). The stent can form uniform thickness struts (see U.S. Pat. No.: 5342348).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (WO 98/30255) in view of Shanley (Pub. No.: US 2002/0082680)

17. Kaplan is explained supra. However, Kaplan lacks recesses in the stent struts. Shanley teaches the use of recesses in stent struts for the purpose of delivering therapeutic agent to site of implantation (see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Kaplan with recesses as taught by Shanley for the purpose of delivering therapeutic agent. Such a modification of Kaplan would be a simple

Art Unit: 3774

substitution of known drug delivery means, and would have occurred using known methods, yielding predictable results.

18. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (WO 98/30255).

19. Kaplan is explained supra. However, Kaplan either lacks or does not specify the total load of melatonin or the time period for release of the melatonin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a total load of melatonin of at least .001 μ g/mm² and a release for at least 6 hours, since both specified ranges would simply be an optimization of the disclosed drug combined with the disclosed stent of Kaplan. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3774

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774